UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,896	04/17/2002	Walter Birchmeier	101195-73	5220

27387 7590 03/29/2006

NORRIS, MCLAUGHLIN & MARCUS, P.A.
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER
NOAKES, SUZANNE MARIE

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,896	BIRCHMEIER ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8* is/are pending in the application.

4a) Of the above claim(s) *5-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-16-2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species election of cefamandole (selected from the positive list 1A) in the reply filed on 12 January 2006 is acknowledged. The traversal is on the ground(s) that the four compounds from the positive list 1A all share a common chemical motif, the cefamandole-scaffold, and all act of inhibit beta-catenin binding. This is not found persuasive because while each compound of 1A may share a common motif, each has a separate and patentably distinct structure and function.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

2. Claims 2-4 are pending and under examination. Claims 5-8 are pending and withdrawn from further consideration as being drawn to non-elected inventions.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 16 July 2002 has been considered by the examiner. See signed and attached PTO-1449.

Claim Objections

4. Claims 2-4 are objected to because of the following informalities: the claims contain material that is non-elected subject matter. The claims should be amended to

remove the non-elected material or alternatively, the claims should be cancelled and rewritten to exclude the non-elected subject matter. Appropriate correction is required.

5. Claims 2-4 are objected to because of the following informalities: The claims are replete with grammatical errors such as run-on sentences, no conjunctions used when required, sentence fragments and overall sentence construction that suggests a direct translation from German to English (e.g. verbs and participles appearing at the end of sentences). Appropriate correction is required.

Specification

6. The disclosure is objected to because of the following informalities: the content of the specification is objected to for improper organization and headings. The following is provided as a general guideline:

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of

electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in

37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the step of modifying the identified compounds by adding

acid groups to said compounds, if necessary, as recited in claims 3 and 4 are not supported anywhere in the specification.

8. The disclosure is objected to for overall informal content. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The aim of this invention is providing new agents for the treatment of tumors and aberrant the development of tissues and organs (p. 4, 3rd paragraph, 1st line); see any of the claims. Appropriate correction is required.

9. The disclosure is objected to because of the following informalities: The brief description of drawings heading on page 12 lacks a proper heading.

Appropriate correction is required.

Claim Interpretation

10. The overall lack of consistent and correct grammatical English imposes the burden of claim interpretation upon the Examiner in the best reasonable manner possible. As such, and as a suggestion of the standards expected by the United States Patent and Trademark Office, the following interpretation is provided to make clear how, for instance, claim 2 has been examined, and also as a suggestion for future amendments to claim 2. The examiner also suggests drafting claims 3 and 4 in a similar manner.

Claim 2 (interpretation): A method for detecting substances that prevent the selective binding of beta-catenin with a protein or proteins selected from the group consisting of LEF-1/TCF transcription factors, APC and conductin/axin; said method comprising the following steps;

a) identifying hydrophobic pockets in the vicinity of essential binding sites in the beta-catenin molecule,

b) fitting substances into said pocket, and

c) synthesizing said substances and testing for prevention of binding.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2-4 are objected to because of the following informalities: The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Appropriate correction is required.

13. Claim 2 recites the limitation "....are identified and subsequently therapeutic substances" in reference to the substances recited earlier in the claim. There is insufficient antecedent basis for this limitation in the claim because in the first instance of the recitation of 'substances' in the claim, said substances are not termed as therapeutic.

14. The term "vicinity" in claims 2 and 4 is a relative term which renders the claim indefinite. The term "vicinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. When working with protein crystal structures, as it appears that these claims are drawn to in-part, a matter of angstroms can be “in the vicinity”; likewise, a few angstroms either way can also mean that it is nowhere near the vicinity of essential binding sites.

15. Claims 3 and 4 recites the limitation "B-catenin mutants" in reference to the method of identifying inhibitors of B-catenin. There is insufficient antecedent basis for this limitation in the claim because B-catenin mutants are neither recited in claim 2 nor is the method drawn to the identification of any mutants.

16. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to “mutants of beta-catenin”, it is unclear whether the mutants are identified in the method of claim 2, or alternatively, if the “mutants” were pre-determined elsewhere, or through analysis of the crystal structure.

17. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amino acids identified which mark the essential binding site is indefinite because it is unclear whether the beta-catenin is from any particular source or species, such as that from murine or rather from human etc. The sequences

from various species are not 100% identical and thus it is unclear and indefinite to claim specific amino acids which has no reference sequence or source.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

19. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Birchmeier et al. (DE 19909251 A1 – cited on the IDS) as evidenced by Huber et al. (Cell, 1997, 90:871-882). Birchmeier et al. teach identifying regions which interact with beta-catenin and LEF-1/TCF4, APC, conductin and E-cadherin by first performing site-directed mutagensis in beta-catenin, which subsequently partly identifies the critical binding areas between beta-catenin and conductin (see p. 3, lines 29-38 and Table 2, p. 8). It was found that the critical binding areas of beta-catenin and LEF-1/TCF4, APC, conductin and E-cadherin all overlap. Following this characterization, the crystal structure of beta-catenin armadillo region, which was solved by Huber et al. in 1997, is used by Birchmeier et al. to characterize the interaction domains of beta-catenin and LEF-1/TCF4, APC, conductin and E-cadherin (see p. 4, lines 8-34), followed by the synthesis of peptides which will inhibit the binding of beta-catenin with conductin, APC

and/or LEF-1/TCF4 (see p 3, (b)); the inhibition can be checked, for instance with an ELISA assay (see p. 4, section 3.). Thus the claimed limitations within the claims have been adequately described.

20. Claims 2 and 3 are rejected under 35 U.S.C. 102(d) as being barred by applicant's German patent (DE 19909251 A1). The teachings of Birchmeier et al. are described above. The DE 19909251 A1 patent was published August 26, 1999 which is more than 12 months prior to the US filing date of September 7, 2000.

Conclusion

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMN
20 March 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER